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14. ABSTRACT <p>Posttraumatic stress disorder (PTSD) is considered a major public health problem in the U.S. due to its high prevalence and the high rates of disability associated with the disorder. For thousands of veterans, PTSD is a chronic disorder, resulting directly from military service that causes substantial psychological suffering and social disability. Barriers to PTSD care include poor access, mistrust, and lack of benefit from traditional treatments.</p> <p>Evidenced-based treatments like Prolonged Exposure therapy (PE) are very effective. Unfortunately, these treatments are not widely available, as a large proportion of veterans live in rural communities and have poor access to specialized mental health care. The VA hospital system currently supports sophisticated telemedicine technology that can provide PE to veterans in their home communities. The proposed project will assess the quality of PE provided via telemedicine and its impact on outcomes, and is, therefore, directly related to the VA's and DOD's mission to provide advanced, accessible, and high quality health care to all eligible veterans, regardless of place of residence: "Right care in the right place, at the right time."</p>					
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Annual Technical Progress Report

INTRODUCTION:

Background: Posttraumatic stress disorder (PTSD) is considered a major public health problem in the U.S. because it has fairly high prevalence and because people with PTSD often have problems with their work, relationships, and health. There are effective treatments for PTSD, such as prolonged exposure therapy (which works by inviting people to revisit their memories of traumatic events and to face objectively safe situations they have avoided). However, individuals with PTSD may not get the treatment they need because they live in rural locations with no trained clinicians or because they have transportation problems (for example, the distance makes frequent travel unfeasible or they cannot afford gas). Some individuals with PTSD do not feel comfortable driving (due to fears of roadside bombs) or they may feel uncomfortable in formal hospitals or other crowded places. One new method of giving treatments is by using interactive video equipment (called "telemedicine"), so that the patient and his therapist can talk with each other and see each other over a monitor (like a two-way television screen).

Objectives/Rationale: The goal of the study is to compare exposure therapy in a usual format (face-to-face, in-person therapy) to the therapy in a telemedicine format. This project will help determine whether telemedicine can be used to provide needed therapies to veterans with PTSD in remote locations. Study Design: 250 military veterans with PTSD will receive exposure therapy either by telemedicine or in-person care. Veterans will be enrolled from the primary care and mental health clinics at the San Diego VA Healthcare System. Therapy will be provided over 12 weekly sessions lasting 90 minutes each. PTSD symptoms will be measured before treatment begins, at the completion of therapy, and at a 6 month follow-up assessment. Learning and memory tests will be given before treatment begins to examine whether cognitive functioning influences treatment outcome, and at the end of therapy veterans and therapists will be asked how satisfied they were with each type of treatment.

BODY:

In the first year of the project (the preparation period), we have hired and trained staff, developed our assessment protocols, and purchased and tested equipment. We have also begun the recruitment and enrollment of research subjects.

We hired two Independent Clinical Evaluators (ICEs), 10 study therapists, a statistician, a Study Coordinator, and a Research Assistant. We have spent many hours training these individuals in their respective duties, as detailed below.

We consulted with experts (Drs. Edna Foa, Patricia Resick, and Murray Stein, among others) to refine and expand our assessment protocol. As we described in previous reports, we retained our primary outcome measures and we added some questionnaires while working to minimize subject burden.

I developed recruitment protocols and more detailed, written screening protocols for our Study Coordinator (Janel Fidler, MA) to use to determine potential subject eligibility during phone screens. We developed a color recruitment brochure, which we have

distributed to clinical and administrative staff and set up in clinic waiting rooms. Ms. Fidler attends the PTSD clinic weekly team meetings to become familiar with the staff and the procedures within each clinic, and she has met with primary care staff to inform them of the study as well.

We have specified the details of each of the assessment meetings and the order of assessments within those meetings. Specifically, we designed two assessment meetings (to reduce fatigue) at pre-treatment and post-treatment. The first meeting includes informed consent, verification of eligibility, and diagnostic interviews (the Structured Clinical Interview for DSM – SCID- for psychiatric disorders in the categories of mood, anxiety, and alcohol/substance abuse and the Clinician-Administered PTSD Scale – CAPS- for PTSD diagnosis and severity).

At the end of the first meeting, veterans are given a questionnaire packet to take home to complete before the second assessment meeting. The questionnaire packet has been designed for ease of reading and flow. For example, the packet begins with simpler questions (demographics) and leads to potentially more sensitive questions about psychiatric symptoms. We also grouped measures together based on period assessed (e.g., last week, last month, lifetime), and our staff members completed the packet before administering it to veterans in the study to ensure that the instructions and the questions were clear and readable.

The second assessment meeting includes neuropsychological testing and a few remaining questionnaires. The neuropsychological battery, focused on executive functioning deficits, includes 3 subtests from the Delis-Kaplan Executive Function System (D-KEFS; Verbal Fluency, Color-Word Interference, and Trails), the California Verbal Learning Test (CVLT), the WAIS digit span subtest, the Rey-Osterrieth Complex Figure Test, and the Wechsler Test of Adult Reading (WTAR; to assess premorbid cognitive ability).

I trained the ICEs in the MINI (for screening bipolar disorder and psychosis), the SCID, the CAPS, and the 8 neuropsychological tests used in this study, using slides of information, videos, user's guides, and role-plays. We are videotaping diagnostic assessments so that we can determine initial and ongoing reliability (intraclass correlations) with the gold-standard criterion rater.

I interviewed over 50 therapists from the San Diego community to obtain the 10 for the study. These therapists are licensed psychologists and Marriage and Family Therapists (MFTs) who had clinical experience and a strong interest in learning Prolonged Exposure Therapy (PE), the intervention used in the study. In January 2009, we brought out Dr. Edna Foa to conduct a 4-day training in PE for the study therapists. We prepared binders with all materials and provided therapy manuals and DVDs used in the treatment to all therapists. In addition to information about PE, we gave therapists additional information about the study and provided initial training in how to use the telemedicine equipment. This training went very well, and the study therapists reported a good understanding of the therapy and the study protocol. I am consulting with the study therapists in two

separate one-hour group meetings each week to help them maintain their adherence to the treatment.

As one of 18 national Trainers for PE in the VA Healthcare System, I developed a specific PE protocol for the study, including a Session Checklist, Motivational Enhancement interview, and standardized forms for each session.

We have weekly meetings for training, communication of problems and progress, and goal-setting. We conduct these meetings via the telemedicine equipment to help familiarize the staff with the technology and troubleshoot as needed. These meetings have been invaluable in identifying targets for the study and getting updates from staff. We have also tested each telemedicine unit to detect problems with lighting and imaging, and we have created blue backgrounds to place behind therapists and research subjects to obtain clear facial images.

We have had regular correspondence with the UCSD Human Research Protections Program, the VA Research and Development Subcommittee, and Karen Eaton, MS at the Human Research Protection Office (HRPO), Office of Research Protections (ORP), United States Army Medical Research and Materiel Command (USAMRMC) to prepare for the implementation of the randomized clinical trial. We obtained approval to begin the study from the UCSD IRB and the VA Research and Development Subcommittee, and on May 20, 2009 we were approved by the HRPO to start enrolling subjects. Since that time, we have screened 23 veterans. Of these, we are awaiting returned calls from 5, 2 were not eligible due to psychosis or mania, 5 were not interested in the study, 3 are eligible and are waiting for medications to stabilize before beginning the study, and 8 are enrolled in the study. Recruitment, screening, assessment, and treatment are progressing well.

We obtained three offices to use in La Jolla from the Veterans Medical Research Foundation (for the therapists to use for both face-to-face visits and telemedicine visits) and one office in each of the remote sites (Vista, Escondido, and Chula Vista). We equipped these new offices with telephones, fax machines, and computers for the project.

We tested several makes and models of telemedicine equipment. We trained the staff (including the study therapists) in the use of this equipment, in coordination with our co-investigators who are experts in telemedicine (John Chardos, MD, and Nilesh Shah, MD) and Ron Schmidt (a national telemedicine training specialist for the VA).

We purchased necessary neuropsychological tests, office supplies, laptop computers (for administering some neuropsychological tests at the remote sites and showing videos during the psychotherapy sessions when needed), fax machines (for faxing subjects' homework to therapists from remote sites), PE therapy manuals, and digital recorders (for taping therapy sessions and loaning to veterans to review). We purchased cameras, digital tapes, and DVDs so that we can record diagnostic interviews (for rating reliability) and therapy sessions for both supervision locally and adherence ratings of prolonged exposure therapy by our collaborators at the University of Pennsylvania.

We have constructed a database in Microsoft Access to ease data entry and allow us to query the data and monitor basic information about recruitment. Data will be exported to statistical software packages (SAS or SPSS) for data analysis.

We have arranged for subject payments to be provided in either cash or “scrips” (checks), depending on the location of the therapy.

We have worked with VA Information Technology staff to provide our staff with access to the Computerized Patient Record System (CPRS). This access enables our Study Coordinator to schedule appointments, the ICEs (assessors) to document assessment meetings, and our study therapists to review patient records and document therapy sessions. I created templates for the progress notes for each of these meetings to maximize efficiency and standardize procedures, and I will be co-signing each therapist’s notes to monitor adherence to protocols and any safety issues.

I have developed a “Crisis Protocol” for managing potential suicidal, homicidal, or otherwise dangerous behaviors by research subjects at each site. We expect that these behaviors will be uncommon (as it is in our clinical work with this population), but I wanted to have a guide in place for all of our staff. We have also standardized a system for monitoring and reporting adverse events that may occur in the study.

Researchers and clinicians from across the United States have requested copies of our materials and consultation about clinical and research issues. We have shared information about the PE protocol we have adapted for the study and about our use of telemedicine technology generally to deliver psychotherapy to remote sites. Scientific journals have sought our expertise in these areas as ad hoc reviewers as well.

I invited Leslie Morland, Psy.D., an expert in telemedicine studies of psychotherapy, to our research team meeting in April. We exchanged information about the challenges facing us in this type of research (e.g., technological issues, issues of hiring and training within the VA, and recruiting and retaining subjects across several months of weekly meetings) and the solutions we have devised. Dr. Morland also shared with us information she learned at the Care Coordination General Telehealth Forum (sponsored by the VA Employee Education System) that she attended.

I have presented many papers recently on PTSD and related issues, including presentations about this project, to share our methods and learn from colleagues about additional ways to improve the study (see list in Reportable Outcomes). My co-investigators and I continually review the research literature and during the preparation period we refined our protocol to ensure best practices. Dr. Thorp and Co-Investigators Drs. Zia Agha and Nilesh Shah will also present this project in both poster and paper formats at the Military Health Research Forum. We will be presenting our project among other projects in the category of telemedicine (Dr. Morland will be presenting as well), and we are looking forward to a stimulating exchange of ideas.

Challenges:

The biggest challenges so far have been: (1) getting people hired, due in part to policies in place (or being developed) in the VA, Veterans Medical Research Foundation, and the University of California, San Diego; (2) space and equipment issues, and (3) negotiating the human subjects review process through the different institutions.

The VA (in conjunction with VMRF) had to write new policy about how to hire and endorse therapists who are dedicated to a particular study (they plan to use this new policy for other upcoming studies). Our Research Service and Psychology service have been using our project as a test case for how to integrate community therapists into the VA system and how to grant certain clinical privileges to them as part of their scope of practice. This process took over 5 months, and in turn delayed other necessary tasks (e.g., granting VA name badges and allowing the therapists to access computerized records). We faced similar challenges (and long delays) in hiring our research staff and assessors.

We are fortunate that VMRF provided us with the space we needed to complete the project at our “hub” site in La Jolla, and we have worked with colleagues to reserve space at the remote sites. We tested all of the equipment and media we use in the study (laptop computers, fax machines, cameras, and digital recorders), and that troubleshooting paid off when we discovered minor issues that could have stalled aspects of the study. This testing also helped us to think through the protocol in a more detailed way, which helped us realize which forms and equipment we needed at the remote sites (and the role of the study coordinator at those sites regarding the equipment). For example, we learned that we have to instruct veterans in the use of the digital recorders as part of the therapy protocol (since they are used during every session) and that the Study Coordinator will have to bring a laptop and DVDs (which are shown as part of the therapy) to the remote sites and start those for veterans during particular sessions since the therapist will not be there to do so.

As stated in previous reports, our local VA has faced particular challenges for research, which has entailed a rebuilding of the Research Service and reworking the research reviewing and monitoring process. This has involved hiring new staff, developing many new forms and policies, and the formalization of monitoring processes. Although there have been many improvements in the process over the past year, the transition has resulted in many frustrating delays and redundant tasks for investigators. As the research system continues to evolve, however, our team has learned of people at the VA who can streamline tasks and who are good at following through on our requests.

The biggest anticipated challenge to this large study may be recruitment. The bulk of our research subjects will come from returning veterans (OIF/OEF), and clinically this cohort has been shown to be difficult to recruit and retain. Moreover, there are now several clinical PTSD studies recruiting in the VA, and these will compete for subjects with this project. Nonetheless, I expect that our broad inclusion criteria will enable us to reach our recruitment goal and the team is well trained in ways to maximize retention.

Another challenge is scoring, entering, and checking our very large data set with one research assistant. As mentioned, we have constructed the database for our study, and discovered that we have over 2,000 individual variables (e.g., questions on measures) for each participant. It would take many hours for our research assistant to enter the data by hand, and that also presents a higher probability of human error. We have an opportunity to use Optical Character Recognition service (much like a Scan-Tron format). This would greatly speed up the data entry process, and the error rate is less than .05%. We are discussing this possibility with the Grant Officer's Representative, Dr. Kimberly Del Carmen, and we have obtained a price quote for our project of \$45,262.50. We believe this service would enable our research assistant to augment the work of our study coordinator in others ways (e.g., compiling assessment and treatment packages and assisting research subjects at remote sites when the Study Coordinator is already scheduled with another subject).

Due primarily to the delay in hiring staff, we have a budget surplus this year. However, we expect that now that we have all staff hired, subjects to be paid, adherence ratings to begin, and potentially the Optical Character Recognition service to be utilized, we will be able to allocate those surplus funds during the next year. We have been working with the VA and VMRF for guidance about the server for the project (our most expensive piece of equipment) as well. There are many new guidelines for Information Technology issues that must be addressed before the server can be used (e.g., compatibility and VA firewall protection), but we hope to purchase that and integrate it within the VA and VMRF framework soon.

We have also discovered that using digital tapes to record all sessions for each participant will become very expensive and will involve extensive labor (e.g., transferring tapes to computers), and we are investigating the possibility of using technology for recording sessions directly onto camcorder hard drives (for later transfer and encryption on our computers) to minimize this cost.

KEY RESEARCH ACCOMPLISHMENTS:

- We have hired the Study Coordinator, two Independent Clinical Evaluators, a Statistician, 10 licensed Study Therapists, and a Research Assistant
- We developed the specific measures used in the study and refined the assessment process.
- We trained assessment staff in the assessment protocol (including the screening process, the informed consent process, diagnostic interviews, questionnaire scoring and interpretation, and neuropsychological testing)
- We trained Study Therapists in Prolonged Exposure Therapy (the treatment) and in the use of the telemedicine equipment. Dr. Thorp meets weekly with the Study Therapists for consultation about the treatment.
- We have purchased, installed, and tested most of our equipment, including the telemedicine units, the cameras, the digital recorders, the laptop computers, and the fax machines to ensure smooth operation during assessment meetings and treatment sessions.

- We have completed the structure for our database in Microsoft Access, including all study variables (e.g., demographic information and all items on questionnaires and diagnostic interviews for all time points).
- We continue to have weekly meetings via telemedicine for training, communication, and goal-setting.
- We have arranged for subject payments to be provided in either cash or “scrips” (checks), depending on the location of the therapy.
- All staff have been granted access to the Computerized Patient Record System (CPRS).
- Dr. Thorp presented at several scientific conferences to share with colleagues about additional ways to improve the methods of this project (see list in Reportable Outcomes).
- We obtained approval from all human subjects committees (VA, UCSD, and HRPO) to begin the project
- We have begun recruitment, screening, assessment, and treatment of subjects
- We have written a "Crisis Protocol" for use if adverse events occur during the project, and we have standardized our monitoring and reporting of adverse events
- Dr. Leslie Morland attended our research team meeting in April 2009 to exchange information about our telemedicine research projects

REPORTABLE OUTCOMES:

Published Abstracts or Presentations by PI in Past Year

None from data generated from this project (data-based presentations are planned after the completion of recruitment).

Publications by PI in past year

None from data generated from this project (data-based presentations are planned after the completion of recruitment).

CONCLUSION:

We feel that we have made good progress in the first year of our project by preparing the foundation for the randomized clinical trial. We have hired and trained the staff so that the administrative, assessment, and treatment teams are well prepared for the tasks ahead. We have begun enrolling subjects in the clinical trial, and we expect that in our next Report we will describe the intensive recruitment during the first part of the randomized clinical trial stage of the project. We believe that this project will add greatly to our knowledge about how best to provide psychotherapy to veterans with PTSD at remote locations.